

REMARKS

I. THE OBJECTION TO CLAIM 11

The Office Action objects to claim 11 asserting that it is dependent on a non-elected claim. In response, Applicants submit that the cancellation of claim 11 obviates any basis for the objection. Reconsideration and withdrawal of the objection to claim 11 are respectfully requested.

II. THE REJECTION UNDER 35 U.S.C. § 112, 2ND ¶

The Office Action rejects claims 10-17 under 35 U.S.C. § 112, second paragraph, as being indefinite for use of the phrase “at least one antiviral pyrimidine and triazine”. In response, Applicants submit that the amendment to claim 10 obviates any basis for the rejection. Reconsideration and withdrawal of the rejection of claims 10-17 under 35 U.S.C. § 112 are respectfully requested.

III. THE REJECTION UNDER 35 U.S.C. § 102

The Office Action rejects claims 10 and 17 under 35 U.S.C. § 102 as being anticipated by WO0027825. Applicants respectfully traverse the rejection.

WO0027825 does not disclose or suggest the claimed invention. The claimed invention is a particle comprising a co-precipitate applied in a layer surrounding a neutral hydrophilic carrier, and comprising at least one antiviral selected from the group consisting of pyrimidine and triazine, at least one surface-active agent, and at least one hydrophilic polymer. WO0027825 discloses particles consisting of a solid dispersion comprising a compound of formula (I-a) and one or more pharmaceutically acceptable water soluble-polymers, wherein the dispersion is prepared by, e.g., mixing a compound of formula (I-a) and a water-soluble polymer; optionally blending additives with the mixture; heating the blend to a homogeneous melt; forcing the melt through a nozzle; and cooling the melt. See pages 18-19. Applicants respectfully submit that the co-precipitate recited in the claim would not be prepared by this process. See, e.g., the present specification which discloses that:

[0004] Solid dispersions are usually obtained using two methods. On the one hand they can be obtained via evaporation of a solution consisting of the active ingredient and an inert polymeric material, and on the other via co-fusion of the aforementioned components, with subsequent solidification. In the former instance, the resulting product is referred to as co-precipitate, in the latter as co-melt. Depending on the preparation technique used, co-precipitates can be a solid mass, but they can also be made in particulate form. Solid dispersions in particulate form have become attractive formulation forms for active ingredients with problematic bioavailability.

WO0027825 also discloses another way of formulating the compounds of formula (I-a) wherein the compounds of formula (I-a) are incorporated in hydrophilic polymers and the mixture is applied as a coat film over small beads. See pages 20-21. Once again, this process would not form a co-precipitate as claimed. Reconsideration and withdrawal of the rejection of claims 10 and 17 under 35 U.S.C. § 102 are respectfully requested.

IV. THE REJECTION UNDER 35 U.S.C. § 102/§ 103

The Office Action rejects claim 11 under 35 U.S.C. § 102/§ 103 as being anticipated by or obvious over WO0027825. Applicants submit that the cancellation of claim 11 obviates any basis for the rejection of claim 11 under 35 U.S.C. § 102/§ 103. Reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. § 102/§ 103 are respectfully requested.

V. THE REJECTION UNDER 35 U.S.C. § 103

The Office Action rejects claims 10-17 under 35 U.S.C. § 103 as being anticipated by or obvious over U.S. Patent No. 6,027,747 (“the ‘747 patent”) in view of WO0122938. Applicants respectfully traverse the rejection.

The ‘747 patent, alone or combined with WO0122938, does not disclose or suggest the claimed invention. The claimed invention is a particle comprising a co-precipitate applied in a layer surrounding a neutral hydrophilic carrier, and comprising at least one antiviral selected from the group consisting of pyrimidine and triazine, at least one surface-active agent, and at least one hydrophilic polymer. The ‘747 patent discloses products prepared by dissolving a therapeutic agent in a volatile organic solvent containing a hydrophilic polymer and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer. See Abstract and column 2, lines 28-35. The ‘747 patent discloses that the organic solvent may also contain a surface-active agent (see column 2, lines 46-52); and that the product may be prepared by spraying the organic solution on a granule made of a carbohydrate and drying (see column 6, lines 31-46). The ‘747 patent contains a laundry list of possible therapeutic agents. See columns 3-5. However, the only examples provided employ progesterone; estradiol; mixtures of progesterone and estradiol; or fenofibrate as actives. The ‘747 patent does not teach or suggest a particle comprising pyrimidine or triazine as claimed.

WO0122938, which discloses pharmaceutical compositions of antiviral compounds that comprise particles obtainable by melt-extruding, spray drying or solution evaporation, also does not disclose or suggest the claimed invention.

Reconsideration and withdrawal of the rejection of claims 10-17 under 35 U.S.C. § 103 as being anticipated by or obvious over U.S. the ‘747 patent in view of WO0122938 are respectfully requested.

VI. THE DOUBLE PATENTING REJECTION

The Office Action rejects claims 10-17 under the judicially created doctrine of obviousness-type double patenting over claims 10-17 of co-pending application serial no. 10/564,786. Applicants respectfully traverse the rejection. Applicants respectfully submit that the present claims, which are directed to a species are patentably distinct from the genus claimed in co-pending application serial no. 10/564,786. Reconsideration and withdrawal of the rejection of claims 10-17 under the judicially created doctrine of obviousness-type double patenting over claims 10-17 of co-pending application serial no. 10/564,786 are respectfully requested.

VII. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested.

Respectfully submitted,

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